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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,037	10/27/2000	Peter Bennett Duff Whyte	U013032-6	8344

7590
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08/05/2009

EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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08/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/702,037	Applicant(s) WHYTE, PETER BENNETT DUFF	
	Examiner DEBBIE K. WARE	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-39, 46 and 75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-39, 46 and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/26/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 28-39, 46 and 75 are presented for examination on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 20, 2009, has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 26, 2009, was filed and received of record. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

The amendment filed May 20, 2009, and extension of time have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Foreign Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on April 30, 1998. It is noted that applicant has filed on June 5, 2006, a certified copy of the patent application as required by 35 U.S.C. 119(b).

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-39, 46 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rendered vague and indefinite for failing to recite a positive step for ingesting the colostrum fraction in the claims. It is unclear when the fraction is ingested per se. Also it is unclear what kinds of subjects are intended by the claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-39, 46 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO/97/16977, AU-A-631136/94, newly cited WO 97/43905 (cited on a PTO-1449 Form already of record), Clark et al, and Ballard et al (US 6,319,522), others cited of record in previous Office action of November 16, 2005.

Claims are drawn to methods of administering colostrum of which is prepared by ultrafiltration and spray drying, and also centrifugation and reconstituting steps can be

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employed for the preparation of the colostrum. Each of the methods employ administering colostrum for changing physical work capacity of a subject.

WO 97/16977 (WO) teach administering effective amounts of compositions containing colostrum, see abstract and page 21, last two lines. Administering is carried out over a period of two weeks, see results of sample times, pages 10-12, Tables 3-6. The administering includes ingestion of a food composition (i.e. yogurt, see page 2, line 1) by a subject (i.e. coffee milk composition administered to a subject, see page 14, lines 5-20). The steps of preparing the colostrum are disclosed to encompass centrifugation to reduce bacteria (page 3, line 4), ultrafiltration (page 4, line 5), The colostrum is prepared so as to retain the immunoglobulin fraction containing antibodies and/or growth factors (see the abstract). The centrifugation is disclosed to take place at a temperature between 55 ° C to 63 ° C, (see page 3, lines 12-14). A heating step is disclosed at temperature between 55 ° C to 63 ° C (see page 3, lines 25-26). An effective amount is administered (page 21, line 31) and 12,500 grams is generated, (page 18, line 18).

AU-A-63136/94 (AU) teaches a colostrum product prepared by a method comprising subjecting colostrum to ultra-filtration to obtain an ultra-filtered colostrum retentate, and recovering the retentate, wherein said product is further subjected to a spray drying process. Note page 1 and claim 1 of the this cited patent. Also the colostrum is subjected to bacterial reduction using centrifugation. Note page 1, claim 2. The colostrum is also subjected to heat, note page 4, line 31. Temperatures used and

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disclosed for preparing the colostrum are less than 64 °C and 72 °C, see page 6, line 15. The colostrum product contains 71.0 % protein, see Table 3.

WO 97/43905 teaches administering colostrum of which is prepared by ultrafiltration and further, is useful for muscle protection or for reducing the muscular recovery phase, see abstract. The colostrum contains 380.0 ng/ml IGF-1, page 12, line 4.

Clarke et al teach colostrum contains IGF-1 (insulin growth factor-1) proteins, at column 44, 1st paragraph, lines 11-12. Further, improved body composition and condition is achieved by the presence of IGF-I levels, administered via colostrum note page 44, lines 1-20. Also reduction of muscle damage during exercise by enhancing healing is disclosed, see page 44-45, all lines and page 46, lines 22-35. Further, it is also disclosed that colostrum is a food and promotes healing of the body composition by ridding the body of toxins and reducing fatigue, note page 51 , lines 1-3. Also improved exercise performance is noted in that it is disclosed that physical stress from exercise causes fatigue, infection, etc. and colostrum reduces these symptoms and infections, note column 44, second paragraph, lines 6-10. Clarke et al also teach that the effectiveness of colostrum depends on how it is produced or processed, note column 15, lines 6-8.

Ballard et al teach reconstituting dry samples in a buffered saline, note column 26, lines 65-67. Colostrum is disclosed at column 27, line 55.

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Claims differ from WO 97/16977 (WO) in that a spray drying step and changing physical work capacity of the subject upon administering the prepared colostrum are not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the above teachings as disclosed to spray dry to prepare the colostrum and then administer it to a subject to change the physical work capacity of the subject disclosed by WO since AU, newly cited WO 97/43905, Clarke et al and Ballard each teach preparing colostrum and AU specifically teaches success for such colostrum preparations using spray drying and WO 97/43905, as well as Clarke et al, teach colostrum can be processed to enhance the presence of proteins and includes IGF-1. Ballard et al specifically teach preparing colostrum to include a reconstitution step. Therefore, to include other steps in the process of preparing colostrum as disclosed by WO is clearly within the skill of an ordinary artisan. WO specifically states that other steps may also be included in the process of their disclosure, note page 3, lines 30-32.

Each of the process steps of spray drying and reconstituting colostrum not specifically disclosed by WO can be performed as recognized by the cited prior art on colostrum with successful expected results. The temperature of centrifugation and heating steps is clearly taught by WO as discussed above. To remove bacteria or reduce bacteria by centrifugation to increase proteins in the colostrum product is clearly taught as well. Ultrafiltration is clearly disclosed. Spray drying is also a recognized step in the art to be performed with success when desired.

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Thus, there is no unexpected successful result obtained by Applicants claimed method of preparation. The colostrum would have been expected to have IGF-1 factor and hence would have been expected to be successful for changing physical work capacity of a subject upon administering it to a subject as a food. Each of these claim features are disclosed by the cited prior art as discussed above. Clarke et al recognized that resistive exercise can be changed by reducing infection and fatigue via administering colostrum as a food to a subject in need of such change or repair. Colostrum having IGF-1 clearly would have provided successful results and based upon the teachings of the cited prior art one of skill would have been motivated to administer it to a subject in need of changing work capacity.

To select for specific effective amounts of at least 0.5 g/g/day or from 1 to 10 g/kg/day for a subject to ingest is within the skill of an ordinary artisan. WO teaches that more than these dosage amounts are obtained from the process, therefore, the dosages as claimed are certainly available in the cited prior art and to determine effective amounts from what is available is well within the purview of a skilled artisan. In the absence to the contrary the claims are rendered *prima facie* obvious.

Response to Arguments

Applicant's arguments filed May 20, 2009, have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231

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USPQ 375 (Fed. Cir. 1986). Clark et al and newly cited WO 97/43905 are combined with other cited prior art to show that improvement of physical work capacity in a subject has been associated with a colostrum fraction. The method steps of preparing the colostrum fraction are disclosed by the primary reference and other secondary references of record. The argument that Clark et al is not credible and would not be accepted upon peer review is noted. However, the reference is not being relied upon as the sole prima facie teaching and is further supported by the newly cited WO reference which shows that a colostrum administered to a subject will afford the ability of the subject to do more exercise and improves recovery from exercise.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Deborah K. Ware/

Deborah K. Ware

Examiner, AU 1651